



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,381	02/26/2008	Daniel H.S. Lee	2159.0430002/EJH/SAC	9649
53644	7590	11/12/2010		
STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C. 1100 NEW YORK AVE., N.W. WASHINGTON, DC 20005			EXAMINER WEGERT, SANDRA L	
			ART UNIT	PAPER NUMBER
			1646	
			MAIL DATE	DELIVERY MODE
			11/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,381	Applicant(s) LEE ET AL.	
	Examiner SANDRA WEGERT	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-10,13-16,18,19,22,24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) 8-10,13-16,18,19,22,24 and 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/25/10,2/12/09,10/12/07,10/12/07,5/31/07,11/16/06,8/23/06,7/14/06.

Art Unit: 1646

Detailed Action

Claims 1, 2, 4, 5, 7-10, 13-16, 18, 19, 22, 24 and 26-29 are pending. Claims 3, 6, 11, 12, 17, 20, 21 and 25 are cancelled. Claims 1, 2, 4, 5, 7-10, 13-16, 18, 19, 22, 24, 28 and 29 are amended.

The following Information Disclosure Statements have been entered and considered, listed by date submitted: 14 July 2006; 23 August 2006; 16 November 2006; 31 May 2007; 12 October 2007; 12 October 2007(b); 12 February 2009 and 25 May 2010. Applicant's election of Invention I (claim 1, 2, 4, 5 and 7) in the Response of 10 August 2010, is acknowledged.

The Applicants traversed the restriction and argued that inventive Groups I-IV share the common technical feature of the polypeptide of claim 1. However, Groups II-III do not share a common technical feature with Group I, since they are different products. Thus, Unity of Invention was not broken; however, according to 37 CFR 1.475(b), applicants may claim multiple categories of product, but only if they comprise one method of making the product (e.g., the nucleic acids and host cells) and one method of using the product (e.g., the method of producing an antibody using the polypeptides). Groups I-IV were restricted properly because applicants are allowed polypeptides, nucleic acids, vectors and host cells comprising the polypeptides, as well as one method of using the polypeptide, if the products and methods relate back to the claimed polypeptide and are of the same scope. The restriction requirement is deemed proper and is therefore made FINAL.

Claims 1, 2, 4, 5 and 7 are under examination in the instant application.

Art Unit: 1646

Informalities

Specification

The disclosure is objected to because of the following informalities:

Claim Rejections

35 U.S.C. § 101-Product of Nature/Gene Therapy

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed invention encompasses non-statutory subject matter. The term “host cell” reads on isolated cells, as well as cells in the context of a multicellular, transgenic organism and cells intended for gene therapy. The specification teaches that the cell comprising a heterologous NgR gene can be used for gene therapy (p. 7, paragraph 0024) indicating said cell becoming integrated into the human being and therefore being an inseparable part of the human itself. The scope of the claims, therefore, encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation “isolated” or “non-human” would be remedial. See 1077 O.G. 24, April 21, 1987.

Claim Rejections- 35 USC § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form

Art Unit: 1646

the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The applied reference has a common Inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C.

102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claims 1, 2, 4, 5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee and Li, 2007 (Publication No. 2007/0065429; serial No. 10/553,669; herein referred to as Lee). Lee claims priority to Provisional application 60/463,424, filed 16 April 2003. Lee discloses each of the polypeptides listed in instant claim 1 (see paragraph 0014), as well as nucleic acids and vectors for gene expression (paragraph 0061, for example). Antibodies made against the claimed polypeptides are discussed at length (p. 4, see paragraph 0037, for example) as are host cells comprising the disclosed nucleic acids (paragraph 0038). Lee also describes methods of immunizing a host in order to produce antibodies (paragraphs 0037 and 0038), as described in claim 7.

Art Unit: 1646

Conclusion: Claims 1, 2, 4, 5 and 7 are rejected for the reasons recited above.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/

3 November 2010

/Gary B. Nickol /

Application/Control Number: 10/567,381

Page 6

Art Unit: 1646

Supervisory Patent Examiner, Art Unit 1646